## REMARKS

The Reply address all issues raised in the Office Action mailed on March 5, 2009. Favorable reconsideration and allowance of the application is respectfully requested.

**Claims Dispositions**

Claims 1, 5, 6 and 8-10 are all the claims pending in the application and rejected.

Applicant thanks the Examiner for withdrawing the previous rejections. Applicant further thanks the Examiner for indicating the elected species is free of prior art.

**Summary of the Office Action**

The Office rejects claims 1, 5, 6, and 8-10 under 35 U.S.C. § 112, first paragraph, as assertedly failing to meet written description requirement. It appears that the Office admits that the subject matter, a sustained-release composition for oral administration comprising the drug nifedipine meets written description requirement, but asserts that no description is provided for isradipine, lovastain, or glypizide.

**Full scope of claims meet written description requirement**

Applicant respectfully submits that the claims in their full scope are described to reasonably convey to one skilled in the art that the inventor, when the application was filed, had possession of the claimed invention

As the Office states, a description of the claimed invention with all of its limitations through words, structures, *figures* and/or diagrams that fully set forth the claimed invention, is required.

The Office asserts that the figures, Tables and description provided by the instant specification are entirely drawn to the inclusion of nifedipine in the claimed sustained-release

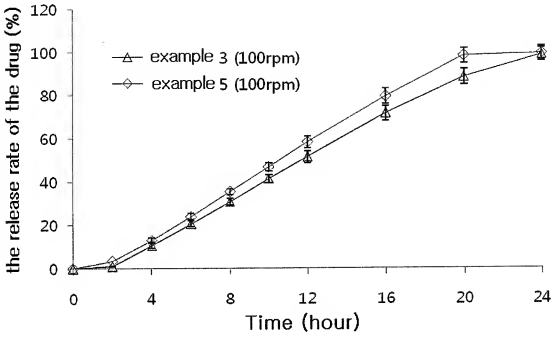
composition. Applicant respectfully submit that *the specification describes that the inventive formulation is designed for maintaining a constant drug level in the blood for 24 hours or more owing to the fact that the drug release rate follows zero order kinetics.* Page 4 of the specification. It also lists representative exemplary embodiments of the drug. Page 5, first full paragraph.

Regarding to the written description requirement, MPEP states that the following factors be considered when analyzing claims for their compliance with the written description requirement: actual reduction to practice; disclosure of drawings or structural chemical formulas; sufficient relevant identifying characteristics; method of making the claimed invention; level of skill and knowledge in the art; and predictability in the art. MPEP 2163 II.A.(a).

Applicant respectfully submits that the specification provides at least four actual reduction to practice as well as methods of making the claimed invention. That is, the specification discloses formulations *comprising lovastatin of Example 4 exhibits zero order kinetics over a period of 24 hours. See Figure 2 of the application.* Furthermore, Table 1 and Examples 3 and 5 of the specification of the instant application clearly show that compositions comprising isradipine and glypizide, respectively, were prepared (see Table 1).

The specification describes various types of the drugs which can be employed in the invention. Therefore, one skilled in the pertinent art would have been able to immediately envisage the claimed kinetic profile from the Figures for the full scope claim 1.

In addition, applicant conducted additional *in vitro* release-tests for the formulations of Examples 3 and 5 comprising isradipine and glypizide, respectively, by employing the same procedure of Test Example 1 described in the subject application, and the results are shown below:




As can be seen from the test results, each of the formulations comprising isradipine and glypizide releases the drug at a constant release rate following zero order kinetics for 24 hours.

A Rule 132 Declaration containing the above data will be provided shortly.

Considering all relevant factors, it is clear that the invention is fully described and the rejection is not sustainable. Withdrawal is respectfully requested.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588.**

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

Sunhee Lee
Registration No. 53,892

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
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CUSTOMER NUMBER

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